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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,054	07/15/2003	Jan K. Caers	17595 (BOT)	8812

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EXAMINER

ANDERSON, CATHARINE L

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/621,054	CAERS ET AL.	
	Examiner	Art Unit	
	C. Lynne Anderson	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/11/03, 11/23/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Gardiner (4,228,796).

Gardiner discloses a device 10, as shown in figure 1, comprising a material 12 with an upper face, a lower face, and a plurality of perforations extending completely through the material. The device is for assisting in making injections, and therefore is fully capable of being used to assist hyperhydrosis therapy.

With respect to claims 2 and 8, the material 12 has an exterior border that is not perforated, as shown in figure 1.

With respect to claims 3 and 9, the material 12 is flexible to that the exterior border is in contact with a dermal area during use, as shown in figure 1.

With respect to claims 4-5 and 10-11, a first group of perforations, the columns, are spaced apart by a first uniform distance. A second group of perforations, the rows, are spaced apart by a second uniform distance that is not equal to the first.

Claims 1-2, 4-8 and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Whitmore, III et al. (6,036,632).

Whitmore discloses a device 10, as shown in figure 1, comprising a material 14 with an upper face, a lower face, and a plurality of perforations 12 extending completely through the material. The device is for assisting in making injections, and therefore is fully capable of being used to assist hyperhydrosis therapy.

With respect to claims 2 and 8, the material 14 has an exterior border that is not perforated, as shown in figure 1.

With respect to claims 4-5 and 10-11, a first group of perforations, the columns, are spaced apart by a first uniform distance. A second group of perforations, the rows, are spaced apart by a second uniform distance that is not equal to the first.

With respect to claims 6-7 and 12-13, the perforations have a first end opening at the upper face and a second end opening at the lower face, wherein the diameter of the first opening is greater than the diameter of the second end, as shown in figure 4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker (US 2002/0086036) in view of Gardiner (4,228,796).

Walker discloses all aspects of the claimed invention with the exception of the use of a device having a plurality of perforations. Walker discloses in paragraphs [0087]-[0088] a method for assisting in hyperhydrosis therapy comprising determining a

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dermal area of a patient which exhibits hyperhydrosis by use of an iodine starch test, marking the area to be treated, and injecting botulinum toxin at the location of the mark.

Gardiner teaches the use of a device comprising a material having an upper face, a lower face, and a plurality of perforations to assist in marking a dermal area to be given multiple injections, as disclosed in column 40-43. The device allows the user to mark areas that need to be injected and identify areas that have already been injected, as disclosed in column 1, lines 29-39.

It would therefore be obvious to one of ordinary skill in the art at the time of invention to employ the device of Gardiner in the method for assisting hyperhydrosis therapy of Walker to allow for the marking of areas that need to be injected and identification of areas that have already been injected.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patents 4,362,157 and 3,999,504 disclose devices having a plurality of perforations for assisting injections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Lynne Anderson whose telephone number is (571) 272-4932. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLA

cla

March 2, 2006

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

